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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/632,008

07/31/2003

Robert E. Richard

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EXAMINER

KENNEDY, SHARON E

ART UNIT

PAPER NUMBER

1615

MAIL DATE

DELIVERY MODE

03/18/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/632,008	Applicant(s) RICHARD ET AL.	
	Examiner Sharon E. Kennedy	Art Unit 1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 19 February 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1 and 4-23 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1 and 4-23 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action or the MPEP.

Claim Rejections - 35 USC § 102

Claims 1, 8-12, 14-17, 21-23 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Crivello, US 4,584,356. Crivello exemplifies that polysiloxane-polystyrene block copolymers are well known. See the abstract. Uses include controlled release drug carriers (column 5, lines 5-6). Regarding claim 8, Crivello does not appear to disclose elongation at break data, but in view that the polymers are the same, and an elongation at break of at least 25% is a modest figure, the examiner takes the position that the Crivello copolymer has the same degree of elongation. Similarly, regarding the transition temperatures, in view that the same polymer blocks are disclosed, the glass transition temperatures must also be the same.

Claims 1, 8-19, 21-23 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Kumar et al., US 5,057,619. Kumar exemplifies that polysiloxane-block copolymers are well known. See the abstract. The preferred block copolymers may include styrene, methyl methacrylate, methyl acrylate, etc.. See column 9, lines 7-12. These are copolymerized with siloxane (column 9, lines 40) +. Uses include controlled release drug carriers (column 4, lines 57-58). Regarding claim 8, Kumar does not appear to disclose elongation at break data, but in view that the polymers are the same,

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and an elongation at break of at least 25% is a modest figure, the examiner takes the position that the Kumar copolymer has the same degree of elongation. Similarly, regarding the transition temperatures, in view that the same polymer blocks are disclosed, the glass transition temperatures must also be the same.

Claim Rejections - 35 USC § 103

Claims 4-7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Crivello '356 in view of Kamath et al., US 6,335,029. Crivello exemplifies that the claimed block copolymer is notoriously old and suggests that it is useful as controlled release drug carriers, medical tubing, biomedical prosthesis, etc. Crivello does not explicitly state that the copolymer is useful as a drug release coating on a medical device, Crivello briefly states that it is useful as a "controlled release drug carrier" (column 5, lines 5-6). Kamath exemplifies that it is known to provide drug carrier coatings comprising various polymers such as siloxane (column 6, line 46) on an implant such as a stent. It would be obvious to one of ordinary skill in the art to use the Crivello block copolymer as both a coating and a drug carrier as exemplified by Kamath. Regarding claims 6 and 7, Crivello briefly states that the block copolymer is useful as a drug carrier but does not further elaborate. Kamath discloses the various intended locations and drug types. It would be obvious to use the Crivello drug delivery device in the recited parts of the body and incorporate the various drugs as dependent upon patient need.

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Claim 20 is rejected under 35 U.S.C. 103(a) as being unpatentable over Crivello '356 in view of Zukosky et al., US 4,616,064. Claim 20 requires that the device be sterilized with sufficient radiation to kill pathogens. Crivello does not disclose sterilization, but in view that the device is a medical device, some sort of sterilization is inherent. Zukosky discloses polymeric compositions, particularly block copolymers comprising polysiloxane and polycarbonate or urethane or amide blocks, and states that they are useful for forming medical tubing which can be radiation sterilized (column 1, line 30). Accordingly, since Crivello discloses the copolymer as a medical tubing or other device, and Zukosky discloses that the polysiloxane copolymers used in Crivello may be radiation sterilized, it would be obvious to one of ordinary skill in the art to radiation sterilized the Crivello medical devices since some sort of sterilization must be performed to protect the patient.

Claim 20 is rejected under 35 U.S.C. 103(a) as being unpatentable over Kumar '619 '356 in view of Zukosky et al., US 4,616,064. Claim 20 requires that the device be sterilized with sufficient radiation to kill pathogens. Kumar does not disclose sterilization, but in view that the device is a medical device, some sort of sterilization is inherent. Zukosky discloses polymeric compositions, particularly block copolymers comprising polysiloxane and polycarbonate or urethane or amide blocks, and states that they are useful for forming medical tubing which can be radiation sterilized (column 1, line 30). Accordingly, since Kumar discloses the copolymer as a medical tubing or other device, and Zukosky discloses that the polysiloxane copolymers used in Kumar may be radiation sterilized, it would be obvious to one of ordinary skill in the art to radiation

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sterilized the Kumar medical devices since some sort of sterilization must be performed to protect the patient.

Response to Arguments

Applicant's arguments with respect to claims 1, 4-23 have been considered but are moot in view of the new ground(s) of rejection.

Contact Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sharon E. Kennedy whose telephone number is 571/272-4948. The examiner can normally be reached on Monday-Thursday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward, can be reached on 571/272-8373.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Sharon E. Kennedy/

Sharon E. Kennedy
Primary Examiner
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